IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT
No. 21-2077

AVAIL VAPOR, LLC, BLACKSHIP TECHNOLOGIES DEVELOPMENT, LLC, and BLACKBRIAR REGULATORY SERVICES, LLC, Petitioners, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Respondent.	Oral Argument Held on October 25, 2022

PETITIONERS' REPLY IN SUPPORT OF MOTION FOR COURT TO TAKE JUDICIAL NOTICE OF FDA'S OCTOBER 26, 2022 PRESS RELEASE

In describing the process it utilizes for reviewing premarket tobacco applications ("PMTAs") for all flavored ENDS products, FDA underscores the policy shift it undertook without warning or consideration of applicants' reliance interests after the application deadline. FDA contends that because all non-tobacco flavored ENDS products present a "high risk to youth," applicants must provide robust evidence that their products are likely to promote complete switching from combustible cigarettes or are likely to significantly reduce cigarette use beyond that facilitated by tobacco-flavored ENDS products. FDA also takes the position that it

will only consider marketing and sales-access restriction plans if an applicant conducts a longitudinal study that presents such comparative efficacy evidence. FDA will not seriously consider such marketing and sales-access restrictions to potentially ameliorate the "high risk to youth" because, it has concluded, such restrictions are ineffective at reducing youth initiation for all flavored products.

FDA's approach to weighing risks and benefits—which the agency never announced with any level of specificity approximating its current demands prior to August 2021—overlooks that there is zero evidence that youth have ever used any of Avail's bottled e-liquid products and that the government's own National Youth Tobacco Survey ("NYTS") results suggest that youth use all bottled e-liquid products at rates far lower than cartridge-based and disposable ENDS. Pet. Br. at 40-43, Pet. Reply Br. at 8-11. The new approach also ignores that FDA itself emphasized the features common to cartridge-based and disposable ENDS, and not found with bottled e-liquids, such as small size, concealability, ease of use for the uninitiated, and high nicotine content, in its 2020 Enforcement Guidance in explaining why cartridge-based devices were particularly attractive to youth, JA104-105 (while suggesting that flavored bottled e-liquids were not and prescribing marketing plan features (many of which Avail adopted) that would be "adequate measures" to prevent youth access, JA110-111). Regardless of whether these positions were justified or are entitled to deference, there can be no dispute that FDA

changed its policy and positions without any contemporaneous announcement or any consideration of applicants' reliance interests after the PMTA submission deadline because its own guidance and proposed PMTA rule had used terms such as "critical" to describe the importance of marketing and sales-access restriction plans, 84 Fed. Reg. 50566, 50581, but FDA now says that they make no significant difference at all for any flavored ENDS products.

Regardless of whether FDA properly concluded in its TPL report, JA31, that all flavored ENDS products—be they bottled e-liquids, cartridge-based devices, or disposable devices—are equally attractive to youth, because FDA changed its position on the issue after the submission deadline, the MDO should be vacated and the issue remanded to FDA to allow Avail a fair opportunity to meet the new specific comparative efficacy standard that FDA has established through an additional longitudinal study along with consideration of Avail's marketing and sales-access restriction plan (including the unique components such as the lack of flavor descriptors on product labels highlighted at oral argument). Remand and a fair opportunity for Lotus to meet FDA's new requirements are necessary because, based on FDA's "sliding scale" approach, an overstatement of the risks to youth necessarily artificially raises the bar for showing the benefits to adult cigarette smokers by way of switching and/or cessation for flavored ENDS products compared to tobacco-flavored ENDS products. *See Sea "B" Mining Co. v. Addison*,

831 F.3d 244 (4th Cir. 2016) (finding prejudicial error in black lung appeal where ALJ failed to consider all CT scan evidence suggesting absence of black lung because ALJ failed to properly weigh or explain CT scan evidence as a whole, including against contradictory x-ray evidence).

By secretly changing the assumptions and conclusions that underlay its weighing of the risks and benefits of marketing flavored bottled e-liquids from its 2020 Enforcement Guidance (to the extent applicants should have even considered it as relevant to the preparation of PMTAs), the 2019 PMTA Guidance, and the proposed and final PMTA rules through its August 17, 2021 internal memorandum, JA77-78, and TPL report that supported the MDO issued to Avail, JA31, FDA ignored Avail's and other applicants' reliance interests and engaged in prejudicial error.

Respectfully submitted,

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LLC; and Blackbriar Regulatory Services, LLC

CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2022, a true and correct copy of the foregoing Petitioners' Reply in Support of Motion for Court to Take Judicial Notice of FDA's October 26, 2022 Press Release was filed with the Clerk's Office for the United States Court of Appeals for the Fourth Circuit using the CM/ECF system and thereby served via electronic mail on all counsel of record.

/s/ Eric N. Heyer
Eric N. Heyer

CERTIFICATE OF COMPLIANCE

I hereby certify that Petitioners' Reply in Support of Motion for Court to Take Judicial Notice of FDA's October 26, 2022 Press Release complies with the type-volume requirement set forth in Federal Rule of Appellate Procedure 32. The word count feature found in Microsoft Word reports that Petitioners' Motion to Supplement the Administrative Record contains 690 words, excluding the items exempted under F.R. App. P. 32(f).

The Reply complies with the typeface and typestyle requirements of Federal Rule of Appellate Procedure 32 because this document has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font.

/s/ Eric N. Heyer
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